REMARKS

This application was pending with 6 claims. In the December 10, 2003 Action, the Examiner:

1) objected to claim 1 for certain typographic errors;

2) rejected claim 1 under 35 U.S.C. § 102(b) as being anticipated by Kieval et al. U.S. Pat. No. 5,626,620 ("Kieval"); and

3) objected to claims 2-6 as being dependent upon rejected claim 1, but allowable if rewritten in independent form.

In this response, applicants have amended claim 1 to correct the typographic errors noted by the Examiner, without changing the scope of the invention. These corrections are believed to render the Examiner's objections moot. The Examiner's indication that claims 2-6 reflect patentable subject matter is noted with appreciation. We respectfully traverse the Examiner's prior art rejection and request reconsideration of this application in light of the foregoing amendments and the following.

THE EXAMINER'S REJECTIONS BASED ON KIEVAL SHOULD BE WITHDRAWN

Applicants' invention is directed to an active implantable medical device, in particular a pacemaker, defibrillator, cardiovertor, or a multisite device, that is able to detect a risk of a fusion situation. We note that the applicants have defined a "fusion situation" as a "risk of fusion" (see specification at p. 4), which is different from a situation when fusion has been detected to exist. In one preferred embodiment, a fusion situation is detected based on an analysis of a sequence of successive cardiac cycles for which the atrio-ventricular delay (AVD) is modified from one cycle to the next (AVD, AVD + 31, AVD + 63) for a number of cycles.

The presence or the absence of a spontaneous ventricular event (R) occurring inside the atrio-ventricular delay thus modified is determined, and the existence of a risk of fusion is determined in the event of the occurrence of a spontaneous ventricular event during at least one of the cardiac cycles of the sequence. Advantageously, the detected risk of fusion can be used to control the operation of implant, for example, by improving signal capture by testing capture at times when there is no detected risk of fusion.

The Kieval reference relied on by the Examiner is not directed to detecting a risk of fusion. Rather, it is directed to detecting fusion beats that have occurred. Thus, the Examiner's characterization of Kieval as relating to fusion conditions as that term is defined and used in applicants' specification and claims is incorrect. Kieval has nothing to do with and does not teach or suggest:

> means for detecting a fusion situation, said fusion situation detecting means being able to:
>
> > analyze a sequence of successive cardiac cycles by modifying the AVD from a first cardiac cycle to a following cardiac cycle, and
> >
> > detect the presence or the absence of a spontaneous ventricular event occurring inside the modified AVD; and
>
> means for determining an existence of a risk of fusion response to a detected spontaneous ventricular event during at least one of the cardiac cycles of the sequence.

as required by applicants' claim 1 (and claims 2-6 depending therefrom).

Instead, Kieval concerns identifying when fusion beats occur and determining a degree (%) of fusion (how many fusion beats are detected within n events) with a view towards controlling pacing after a certain degree of fusion exists by subsequently adjusting the AVD to reduce fusion events to below a tolerable degree. This disclosure contrasts with applicants' invention, which determines a risk of fusion -- not actual fusion beats -- so that control

parameters that might be adversely affected if determined based on a detected fusion, are not modified when there is a risk of fusion. But, as noted, applicants' disclosure does not involve determining that there has been a fusion event or too many fusion events in a given period.

We also respectfully submit that the Examiner's reliance on Kieval Figure 6A as indicative of disclosing detection of a risk of fusion is wholly misplaced. First, Kieval discloses that at decision block 653, the pacemaker responds to an evoked response and "determines whether there has been a fusion beat." (Keival, Col. 9, lines 58-62). This is a fusion beat during normal operation, not a "risk of fusion" and not a "fusion situation" based on a modified AVD over some cycles as required by applicants' claim 1. Second, Kieval indicates that a fusion is determined, for example, "by detecting a significant decrease in duration of either the QRS waveform from the V sense channel, or the FFRS waveform from the A sense channel." (Kieval, Col. 9, lines 64-67), and the variable that counts the number of identified fusion beats, "FUSECOUNT" is incremented. (Kieval, Col. 10, lines 1-2). Again, Kieval discloses counting fusion beats, not identifying whether there is a risk of fusion. Moreover, this has nothing to do with applicants' search for spontaneous ventricular events during the AVD as the AVD is varied.

With respect to decision diamond 657 relied on by the Examiner (Fig. 6A) (Action p. 2), we respectfully disagree that it reflects any indication of a risk of fusion as that term in used in applicants' specification and claims. Rather, it "determines the percent of fusion beats in the last n cycles (e.g., 10) and whether this percentage is acceptable." (Kieval, Col. 10, lines 1-8). Again, this concerns counting fusion beats, not identifying a risk of fusion. The Examiner's suggestion that past history is predictive of a future risk of fusion (Action p. 2-3) does not withstand scruitiny. First, the Kieval technique for counting actual fusion beats is different from and does not teach or suggest applicants' claimed technique for detecting a risk of fusion.

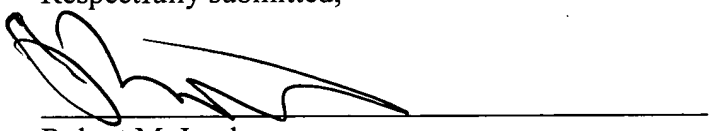
Second, the Examiner's suggestion is counter-intuitive. If Kieval's degree of fusion parameter remains below the threshold, it indicates that the degree of fusion is not significant, and thus no corrective action need be taken, which in turn suggests that no adverse fusion events are anticipated. Conversely, if the degree of fusion parameters is sufficiently high, then corrective action is taken that will reduce the number of fusion events that might occur in the future, thus again resulting in no adverse fusion events being anticipated. We respectfully submit that, in all cases, Kieval fails to identify a risk of fusion as that term is used in applicants' specification and claims and does not anticipate claim 1.

We respectfully submit that the Examiner's rejection for anticipation based on Kieval could only have been made based on having first read applicants' specification and claims. Such a hindsight reconstruction of the art is of course improper, and should be withdrawn.

CONCLUSION

For the foregoing reasons, applicant respectfully submits that applicants have made a patentable contribution to the art. Reconsideration and allowance of this application in light of the foregoing are respectfully requested.

Respectfully submitted,



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